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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,195	03/01/2002	Patricia Anne Nuttall	2488-1-004	8628

7590 09/23/2003

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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/23/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,195	NUTTALL ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 30, 2003 as Paper Number 10* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' response filed June 30,2003 as Paper Number 10 to Office Action mailed May 29, 2003 as paper number 9 is acknowledged and entered.

2. Claims 1-8 are pending.

Restriction/Election

3. Applicants' election with traverse of Group I, Claims 1-5 and 7-8 filed June 30,2003 as Paper Number 10 to election requirement in Office Action mailed May 29, 2003 as paper number 9 is acknowledged and entered. Applicants' traversal is on the grounds that the "Groups I-II drawn to the methods to treat allergic rhinitis can be searched without any hardship to the Examiner because "the search for any of the methods separately" "would require an additional search of the identical classes, wherein the methods are classified". Citing MPEP §§802.01 and 808.02, applicants further argue that "even with patentably different inventions, restriction is not required, unless one of the following: separate classification, separate status in the art or different field of search" conditions are met. Applicants also argue "the groups designated by the Examiner fail to define methods, with properties so distinct as to warrant separate examination and search".

Applicant's arguments regarding the election requirement cited *supra* have been fully considered but are not persuasive because of the reasons of record on pages 2-3 in Office Action mailed May 29, 2003 as paper number 9 and for the reasons below: The search for each of the distinct inventions of Groups I-II have different properties and are not search co-extensive because inventions in each of groups I-II:

(a) are in separate classifications,
(b) have separate status in the art as a separate subject for inventive effect, and
(c) require independent searches, particularly with regard to the literature search.

Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Accordingly, Claim 6 is withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in response to this Office action to expedite prosecution.

4. Claims 1-5 and 7-8 are examined on merits.

Information Disclosure Statement

5. Applicants' Information Disclosure (i.e., IDS) filed July 15, 2002 as paper number 8 has been made of record and considered.

Priority

6. Applicant's claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. Claims 1-8 in the instant non-provisional application (U. S. Application Number 10/087,195) are given the benefit of priority date of 08/24/2000.

Objection To Specification

7. The specification is objected to as failing to provide proper reference to drawings. In specification on Page 9, Lines 27-28, reference is made to Figs 1, 2, 3a-3c and 4a to 4c. However, application contains only Figures 3a, 3c and 4b. Appropriate correction is requested.

Claim Rejections Under 35 U.S.C. § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

9. Claims 1-5 and 7-8 are rejected under 35 U.S.C.§112, first paragraph, because the specification, while enabling for a method to treat allergic rhinitis (See Page 9, Lines 4 to 30 and Figures 3a, 3c and 4b), does not reasonably provide enablement for a method to prevent allergic rhinitis via instantly claimed method of administering the instantly claimed pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification, while being enabling for a method to treat non-infective or allergic rhinitis, since does not particularly illustrate an example of a method to prevent allergic rhinitis via administering a composition comprising "a functional equivalent or an active fragment" of histacalin protein, wherein

MS-HBP1, FS-HBP1, FS-HBP2 or D.RET6 proteins are the histacalin protein, the specification does not reasonably provide enablement to a method to prevent allergic rhinitis via the claimed method of administering the claimed pharmaceutical composition.

From the record of the present written disclosure applicants have merely mentioned administering a variety of compositions comprised of histacalin protein in mixtures with saline to treat allergic rhinitis. While the specification discloses an example where a preparation comprising the claimed composition (i.e., histacalin protein) was administered to human subjects followed by challenging said subjects with a solution of EV 504 or VAC life, there is no recitation of an example where the claimed histacalin protein was not administered and said subjects were challenged with EV 504 or VAC life either before dosing them with the histacalin protein preparations or post administration of histacalin protein (See Page 9, Lines 4 to 30 of the specification of instant application). Thus, no clear data or example is given to demonstrate that said allergic rhinitis was prevented with the administration of claimed histacalin protein composition. Furthermore, example presented in the specification does not clearly demonstrate prevention of allergic rhinitis.

Inventions targeted for human therapy claiming method(s) of treatment and/or prevention of a certain ailment bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatment and/or prevention or prophylaxis of disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to an individual that would in effect "prevent" the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, applicants would have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient of the composition for the administration of the composition intended for a method of therapeutic treatment or prophylaxis. There is no guidance in the specification, other than a method to administer a composition comprising histacalin protein in mixtures with either dH_2O or saline for prevention of aforementioned disease conditions. Moreover, the instant application does not provide a working example providing data that shows that the method and composition of the instantly claimed invention would indeed prevent an event such as the claim designated disease conditions. Thus, applicants have not demonstrated the claimed functional effect of preventing any and all allergic rhinitis.

Accordingly, undue experimentation without a reasonable expectation of success as to how to determine which combination of histacalin protein or MS-HBP1, FS-HBP1, FS-HBP2 or D.RET6 proteins, or a "functional equivalent thereof" or "an active fragment thereof" in pharmaceutically acceptable carrier and in which therapeutic amounts of any or all of the claimed designated components would be effective in the instantly claimed method to administer the instantly claimed composition to obtain the instantly claimed functional effect of preventing allergic rhinitis would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

10. Claims 1-5 and 7-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims. This is because Claim 4 which depends from Claim 1 is directed to a "functional equivalent" or an "active fragment" of histacalin protein, or MS-HBP1, FS-HBP1, FS HBP2 or D.RET6 protein that are administered as therapeutically effective amount in form of a medicament to a patient for the treatment or prevention of allergic rhinitis.

From the record of the present written disclosure, the specification, while enabling for a method to treat allergic rhinitis (See Page 9, Lines 4 to 30 and Figures 3a, 3c and 4b), via administering a composition comprising therapeutically effective amount of histacalin protein; does not reasonably provide said applicability for any or all "functional equivalent" or an "active fragment" of histacalin protein or MS-HBP1, FS-HBP1, FS HBP2 or D.RET6 proteins. Furthermore, the example in the specification demonstrates a method to treat allergic rthinitis comprising administration of a pharmaceutical composition comprising only a few concentrations of only the histacalin protein (See Page 9, Lines 4 to 30 and Figures 3a, 3c and 4b). Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to extrapolate the claimed invention to "functional equivalent" or an "active fragment" of histacalin protein, or MS-HBP1, FS-HBP1, FS HBP2 or D.RET6 protein. Thus, in the absence of demonstrated evidence of record that said pharmaceutical composition comprising "functional equivalent" or an "active fragment" of histacalin protein, or MS-HBP1, FS-HBP1, FS HBP2 or D.RET6 protein would treat allergic rhinitis upon administering of said composition to a patient in need thereof, the claimed invention is not considered enabled.

An ordinary artisan would not be able to practice the invention because undue experimentation will be required to obtain the pharmaceutical activity cited *supra* due to the quantity of experimentation

necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

12. Claims 2-3, 5 and 7-8 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Term, "derived" in claims 2-3 renders those claims indefinite. This term is unclear as well as confusing, and therefore, indefinite because the term does not clearly define as to how similar a material should be to the base material to be called a derivative, i.e. the term does not define the metes and bounds of the claimed subject matter.

- In Claim 5 the limitation "manufacture of the medicament" is recited. There is insufficient antecedent basis for this limitation in the cited claim, because this limitation is not recited in Claim 1 from which Claim 5 depends.

- Claim 7 as recited presently does not in any way advance or limit the method recited in Claim 1 from which Claim 7 depends.

All other claims depend directly from the rejected claims (e.g., 7) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

13. A search for prior art revealed the following references to be closest to the invention claimed in the instant application.

- Bollen, A. et al. May 3, 1995. New Nucleic Acid Encoding Human Histamine H1 Receptor-Useful Diagnostically and for Screening Receptor Binding Drugs. GB 2, 283,239.
- Paesen, G. et al. 27 November 1997. Vasoactive Amine Binding Molecules. WO 97/44451.
- Paesen, G. et al. U.S. Patent 6,6117,312.
- Nuttall. P. et al. June 3, 1999. Histamine and Serotonin binding Molecules. WO 99/27104.

However, all of the above-cited references claim a protein composition obtained from ticks, none of the references discloses a method to treat or prevent allergic rhinitis comprising administering to a subject in need thereof a pharmaceutical composition comprising a therapeutically effective dosage of a histacalin protein, wherein said histacalin protein is obtained from a blood feeding ectoparasite (e.g., tick) and said histacalin protein is MS-HBP1, FS-HBP1, FS HBP2 or D.RET6 protein.

Conclusion

14. No Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

September 20, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER